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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,289	10/29/2003	Kazumi Toyoda	10844-41US (203025)	5130

570 7590 04/10/2007
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2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER

ROZANSKI, MICHAEL T

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/696,289

Applicant(s)

TOYODA ET AL.

Examiner

Michael Rozanski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. With respect to specification and claim objections, the amendments are noted and the objections are withdrawn. However, Applicant's arguments filed March 14, 2007 with respect to claim rejections have been fully considered but they are not persuasive. Applicant argues that Golden et al. (US 5,622,169) do not disclose that the plurality of could be at least three sensors, how the signals from other than two sensors could be used, or if more than two sensors were employed that the signals from the two closest to the permanent magnet would be used for detecting the medical tube. As previously stated below, Golden et al. discloses that a plurality of sensors (two or more) may employed (col. 7, lines 55-56), which encompasses Applicant's limitation that the plurality is at least three sensors. With respect to how the signals from the other than two sensors could be used, it is not evident in the claims that this is a limitation, aside from the sensors becoming active when closest to the permanent magnet. It follows that Golden et al. teach that different types of sensors may be used including Hall-effect, flux-gate, wound-core inductive, squid, magneto-resistive, and nuclear precession sensors (col. 7, lines 52-57). A Hall-effect sensor, for example, is used for proximity switching, wherein the sensor may function as a switch with an on/off mode that 'switches' depending on the proximity to a magnetic field generating means. Therefore, if the plurality of sensors were of the Hall-effect type, then the sensor(s) closest to the permanent magnet would be used while the other sensors would remain in the "off" position.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-9, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by ***Golden et al.*** (US Patent No. 5,622,169). In reference to claims 1 and 9, Golden et al. disclose an apparatus and method for detecting the location of a medical tube within the body of a patient (col. 6, lines 15-17). The apparatus is capable of detecting a position and an orientation of an insertion portion of a medical insertion tool inside a body cavity. The apparatus includes a permanent magnet fixed to the end of the medical tube that serves as a magnetic field generating means (col. 6, lines 32-40). Further, the magnet requires no power source, whereby the undesirable electrical connections necessary for a power source are avoided, and maintains its magnetic field indefinitely, allowing long-term positioning and detection of medical tubes (col. 6, lines 50-57). Therefore, a magnetic field is generated without applying an electric current or conductor. The magnetic field detecting means can detect the magnetic field strength gradient produced by the magnet at distances ranging from several centimeters to several decimeters, and is disposed outside the body cavity (see Fig. 4).

Golden et al. describe a magnetic field strength sensor driver 10, including a first magnetic field strength sensor 10 and a second magnetic field strength sensor 20.

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However, it is also disclosed that a plurality of sensors may employed (col. 7, lines 55-56), which encompasses Applicant's limitation that the plurality could be at least three sensors. It follows that Golden et al. teach that different types of sensors may be used including Hall-effect, flux-gate, wound-core inductive, squid, magneto-resistive, and nuclear precession sensors (col. 7, lines 52-57). A Hall-effect sensor, for example, is used for proximity switching, wherein the sensor may function as a switch with an on/off mode that 'switches' depending on the proximity to a magnetic field generating means. Therefore, if the plurality of sensors were of the Hall-effect type, then the sensor(s) closest to the permanent magnet would be used while the other sensors would remain in the "off" position. Referring to Figure 5, the first sensor 10 includes x, y, and z-axis sensors 101, 102, and 103, respectively, while the second sensor 20 includes x, y, and z-axis sensors 201, 202, and 203, respectively (col. 12, lines 43-49). Therefore, the magnetic field detecting means includes plural magnetic sensors having triaxial directivity, wherein the sensors 10 and 20 with triaxial directivity are formed by combining plural sensors with uniaxial directivity. Furthermore, the triaxial directivity of the plurality of sensors permits the apparatus disclosed by Golden et al. to be capable of detecting a three dimensional position and a three dimensional orientation of the insertion portion of the medical insertion tool.

In reference to claims 5, 6, 7, and 8, Golden et al. disclose a medical tube for insertion into the body. The medical tube is fully capable of being a medical insertion tool selected from among indwelling tools inside the body cavity such as a catheter, a

guide wire, an endoscope or a drainage tube, a biliary stent, or a high calorie transfusion tube (col. 6, lines 15-31).

In reference to claims 3, 4, 11, and 12, Golden et al. disclose a first and second sensor 10, 20. It is noted that several different types of sensors may be used in the practice of the invention, including (but not limited to) Hall-effect, flux-gate, wound-core inductive, squid, magneto-resistive, and nuclear precession sensors (col. 7, lines 52-55). Therefore, the magnetic sensor of the magnetic field detecting means may be a magneto-impedance effect element.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over ***Golden et al.*** in view of ***Haynor et al*** (EP 1181891).

Claims 2 and 10: Golden et al. substantially disclose all features of the current invention but do not specifically disclose sensors equally spaced around a scope to be measured. In the same field of endeavor, Haynor et al. teach a plurality of sensors equally spaced around a scope to be measured (see figure 4). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have

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incorporated teaching of equally spaced sensors in order to allow the sensors to be equidistant from a point within the body for detecting the scope.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show medical instrument location means.

US Patent No. 5,099,845 to Besz et al. disclose a catheter 40 fitted with a radiating coil 41 located in the chest cavity of a patient and a receiving coil array 44 incorporated into a hand-held unit 46.

US Patent No. 5,257,636 to White discloses an apparatus 10 for determining the optimum position of an endotracheal tube, including a magnetic sensing means 22 and an indicator 32.

European Patent No. 1,181,891 to Haynor et al. disclose a device to detect the location of a magnet coupled to an indwelling medical device, including multiple magnetic sensors to provide three dimensional measurement in the x, y, and z directions. The sensors may be spherically arranged around a patient's head (see Fig. 4).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

MR


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER